

MISSOURI BOARD OF EXAMINERS  
FOR HEARING INSTRUMENT  
SPECIALISTS,

Plaintiff,

V.

HEARING HELP EXPRESS, INC.,

Defendant.

No. 04-04068-CV-C-SOW

ORDER

Before the Court are plaintiff's Motion for Summary Judgment (Doc. #17) and defendant's Cross Motion for Summary Judgment (Doc. #18). For the reasons stated below, plaintiff's motion is granted and defendant's motion is denied.

## I. Facts

The parties are in agreement as to the material facts in this case. Plaintiff in this action is the Missouri Board of Examiners for Hearing Instrument Specialists (“the Board”). This agency was created for the purpose of administering and enforcing the provisions of Chapter 346, Mo. Rev. Stat. Defendant Hearing Help Express, Inc. (“HHE”) is an Illinois company that sells hearing aids, custom earmold kits, and hearing aid accessories through the mail in interstate commerce. HHE also sells hearing aids on the Internet through its website ([www.hearinghelpexpress.com](http://www.hearinghelpexpress.com)).

At issue in this case is Mo. Rev. Stat. §346.110.1 which provides that “No person shall:

(1) Sell through the mails, hearing instruments without prior fitting and testing by a hearing

instrument specialist.” The Board is seeking a permanent injunction prohibiting HHE from selling hearing aids through the mail in Missouri without prior fitting and testing by a Missouri-licensed hearing instrument specialist.

Board Member Scott George has testified that the provisions of §346.110.1, Mo. Rev. Stat. Are intended to insure that the purchaser is properly fitted with a hearing aid that will benefit his hearing ability. The Board’s expert witnesses, Dr. Scott Estrem, M.D., and Gilbert Phon, Au.D., testified that the reasons for prohibiting mail order sales of hearing aids relate to the safety and/or effectiveness of the hearing aid device. They explained that audiometric testing would identify any medical conditions that could or should be treated with medical or surgical means rather than by use of a hearing aid. Dr. Estrem and Mr. Phon also testified that the use of a hearing aid for amplification, when inappropriate, could lead to permanent hearing loss from amplification and “overdriving” of input into the ear. They also explained that insertion of a hearing aid could lead to problems if the ear had previously been treated through surgery. Finally, they testified that placement of earmold impression material by the consumer involves a special block placed in the ear canal to protect the eardrum; however, this material can adhere to the eardrum or pockets to the ear drum and cause pain and injury when removed.

It is undisputed that a person does not need to be a resident of the State of Missouri to become a licensed hearing instrument specialist in Missouri. A person can live in Illinois and be licensed in Missouri.

## II. Standard

A motion for summary judgment should be granted if, viewing the evidence in the light most favorable to the non-moving party, there is no genuine issue as to any material fact and the

moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); Rafos v. Outboard Marine Corp., 1 F.3d 707, 708 (8th Cir. 1993) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986)). A defendant who moves for summary judgment has the burden of showing that there is no genuine issue of material fact for trial. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986). A plaintiff opposing a properly supported motion for summary judgment may not rest upon allegations of its pleadings, “but must set forth specific facts showing there is a genuine issue for trial.” Id.

### III. Discussion

#### A. Federal Preemption

Plaintiff argues that Mo. Rev. Stat. §346.110(1), requiring prior fitting and testing by a hearing instrument specialist before a hearing instrument is sold through the mails, is not preempted by 21 U.S.C. §360k. Pursuant to 21 U.S.C. §360k:

- (a) no state . . . may establish . . . with respect to a device intended for human use any requirement - -
  - (1) which is different from, or in addition to any requirement applicable under this statute to the device, and
  - (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

In addition, the Food and Drug Administration regulations regarding hearing aids provide:

- (a) Medical evaluation requirements - -
  - (1) General. Except as provided in paragraph (a)(2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient’s hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical

evaluation must have taken place within the preceding 6 months.

(2) Waiver to the medical evaluation requirements. If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of paragraph (a)(1) of this section provided that the hearing aid dispenser:

(i) Informs the prospective user that the exercise of the waiver is not in the user's best health interest;

(ii) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and

(iii) Affords the prospective user the opportunity to sign the following statement: I have been advised by \_\_\_\_\_ (hearing aid dispenser's name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

(b) Opportunity to review User Instructional Brochure. Before signing any statement under paragraph (a)(2)(iii) of this section and before the sale of a hearing aid to a prospective user, the hearing aid dispenser shall:

(1) Provide the prospective user a copy of the User Instructional Brochure for a hearing aid that has been, or may be selected for the prospective user;

(2) Review the content of the User Instructional Brochure with the prospective user orally, or in the predominate method of communication used during the sale;

(3) Afford the prospective user an opportunity to read the User Instructional Brochure.

(c) Availability of User Instructional Brochure

(1) Upon request by an individual who is considering purchase of a hearing aid, a dispenser shall, with respect to any hearing aid that he dispenses, provide a copy of the User Instructional Brochure for the hearing aid or the name and address of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained.

(2) In addition to assuring that a User Instructional Brochure accompanies each hearing aid, a manufacturer or distributor shall with respect to any hearing aid that he manufactures or distributes:

(i) Provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users;

(ii) Provide a copy of the User Instructional Brochure to any hearing aid professional, user, prospective user who requests a copy in writing.

(d) Recordkeeping. The dispenser shall retain for 3 years after the dispensing of a hearing aid a copy of any written statement from a physician required under paragraph (a)(1) of this section or any written statement waiving medical evaluation as required under paragraph (a)(2)(iii) of this section.

(e) Exemption for group auditory trainers. Group auditory trainers, defined as a group amplification system purchased by a qualified school or institution for the purpose of communicating with and educating individuals with hearing impairments, are exempt from the requirements of this section.

21 C.F.R. §801.421.

Federal preemption language is to be read in context and interpreted narrowly. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 518-19 (1992). “[A]bsent an explicit indication by Congress of an intent to pre-empt state law, a state statute is preempted only where compliance with both federal and state regulations is a physical impossibility or where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” CTS Corporation v. Dynamics Corporation of America, 481 U.S. 69, 78-79 (1987)(internal citations and quotations omitted).

In Smith v. Pingree, 651 F.2d 1021 (5<sup>th</sup> Cir. 1981), the United States Court of Appeals for the Fifth Circuit evaluated a Florida statute that is very similar to the Missouri statute at issue in this case. In Smith, the argument was raised that the Florida statute was preempted by the federal regulatory scheme. Id. at 1022. The Court held that,

[r]ead as a whole, then, the purpose of §801.421 is to insure that the prospective purchaser of a hearing aid is provided with sufficient information to make an intelligent decision as to whether to purchase a hearing aid. This section thus addresses the conditions for sale of hearing aid devices, *rather than the mechanics of properly fitting the device to the patient.*

Id. at 1023 (emphasis added).

The Court noted that the contested Florida statute in Smith set forth ““minimal procedures

and equipment’ required to be used in the ‘fitting and selling of hearing aids.’” Id. (citing Fla. Stat. §468.135 (1979)). The Court held that “the federal regulation does not address the procedures required for fitting the hearing aid to the patient.” Id. at 1024. The Court explained that “[b]ecause here federal regulations did not address the mechanics of fitting hearing aids to patients, the state was free to prescribe minimal procedures to be followed and equipment to be used in the fitting of hearing aids.” Id.

In this case, Missouri’s statute simply provides a procedure for the fitting of hearing aids to the patient. Therefore, it is not preempted by the federal statute or regulations.

B. Commerce Clause

Defendant argues that the Missouri statute violates dormant Commerce Clause. The dormant Commerce Clause prohibits state regulations that discriminate or unduly burden interstate commerce. General Motors v. Tracy, 519 U.S. 278, 287 (1997); Southern Union Company v. Missouri Public Service Commission, 289 F.3d 503, 507 (8<sup>th</sup> Cir. 2002). Under the Commerce Clause analysis, regulations designed for the purpose of economic protectionism are presumptively invalid. *See* Southern Union, 289 F.3d at 507. Where a statute “regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits.” Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970); Southern Union, 289 F.3d at 507.

In this case, Mo. Rev. Stat. §346.110(1) applies equally to domestic as well as foreign corporations. It is not designed for the purpose of economic protectionism. The statute would prevent a hearing aid retailer in Kansas City, Missouri from selling hearing aids through the mail

to Missouri residents in more rural areas of the state.

Therefore, the question before the Court is whether the burden on interstate commerce is clearly excessive in relation to the putative local benefits. Pike, 397 U.S. at 142. States have a compelling interest in the practice of professions within their boundaries and broad power to regulate the practice of professions. Goldfarb v. Virginia State Bar, 421 U.S. 773, 792 (1975). Missouri's statutory scheme for the fitting of hearing instruments benefits consumers of hearing instruments by ensuring that they are properly fitted with a hearing aid, rather than provided with one which might do damage to their ear.

The Court finds that Mo. Rev. Stat. §346.110(1) does not violate the Commerce Clause.

#### IV. Conclusion

For the reasons stated above, it is hereby

ORDERED that plaintiff's Motion for Summary Judgment (Doc. #17) is granted. It is further

ORDERED that defendant's Cross Motion for Summary Judgment (Doc. #18) is denied. It is further

ORDERED that defendant Hearing Help Express, Inc. is permanently enjoined from selling hearing aids through the mail and internet without complying with Mo. Rev. Stat. Section 346.110(1).

/s/Scott O. Wright  
SCOTT O. WRIGHT  
Senior United States District Judge

Dated: 7-21-05